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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/676,380	09/29/2000	Andre T. Baron	07-277	1919
30058 7590 04/14/2008 COHEN & GRIGSBY, P.C. 11 STANWIX STREET 15TH FLOOR PITTSBURGH, PA 15222				
EXAMINER BORGEEST, CHRISTINA M				
ART UNIT 1649		PAPER NUMBER		
NOTIFICATION DATE 04/14/2008		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPPatent@CohenLaw.com
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Office Action Summary

Application No.

09/676,380

Applicant(s)

BARON ET AL.

Examiner

Christina Borgeest

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 18-31 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18-31 is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/88)
- Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Formal Matters

The amendment filed 29 January 2008 is acknowledged. Claim 18 is currently amended. Note that the amendment can be found *ipsis verbis* at p. 32 of the specification as originally filed.

Rejections withdrawn

Claim Rejections - 35 USC § 112, first paragraph – Enablement

The rejection of claims 18-31 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention as set forth at pages 2-5 of the previous Office action mailed 19 September 2007 is withdrawn in response to Applicants' provision of current catalog descriptions of available antibodies for their methods recited in the claims.

Furthermore, the issue raised at pages 4-5 was that that the claims recite MAb R.1 antibodies ***and those that competitively inhibit the binding of MAb R.1 to soluble ErbB1*** (emphasis added) and Mab 528 ***and antibodies that competitively inhibit the binding of MAb 528 to soluble ErbB1*** (emphasis added). Since the claims are drawn to a sandwich assay in which the soluble ErbB1 is captured between the two antibodies (sandwiched), it is not clear how antibodies that competitively inhibit the binding of Mab R.1 to ErbB1 and antibodies that competitively inhibit the binding of Mab

528 to ErbB1 could be employed in this assay. Using such antibodies would inhibit the assay, since MAb R.1 and MAb 528 would be unable to capture the sErbB1. Since Applicants' amended claim 18 to clearly state that the primary antibody #1 is captured (i.e. bound) by the primary antibody #2, the claims recite the steps of a sandwich assay.

Claim Rejections - 35 USC § 112, first paragraph – Written Description

The rejection of claims 18-31 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement as set forth at pages 5-7 of the previous Office action mailed 19 September 2007 is withdrawn in response to Applicants' provision of current catalog descriptions of available antibodies for their methods recited in the claims.

New Objection

Specification

This application is in condition for allowance except for the following formal matters:

The amendment filed 29 January 2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the substitute sequence listing—Appendix A. Applicants state at p. 2, 2nd paragraph of their remarks

that SEQ ID NO: 1 has one amino acid change at position 540 and that the error was duplicated in SEQ ID NOs: 3-6 due to the N-terminus being the same in all sequences and that SEQ ID NO: 2 has 5 separate one nucleotide corrections at various positions. It is not sufficient to simply state that corrections to errors have been made. Applicants must describe the nature of the errors, when they were discovered, and exhibit due diligence in correcting them. See *Ex parte Maizel* 27 USPQ2d 1662, which provides guidance as to how to correct sequence errors.

Applicant is required to correct this issue in the reply to this Office Action.

Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 25 USPQ 74, 453 O.G. 213, (Comm'r Pat. 1935).

A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

Conclusion

Claims 18-31 are free of the prior art, for reasons outlined at p. 8, 1st paragraph of the previous Office action mailed 19 September 2007. Although claims 18-31 contain allowable subject matter, there is the issue of new matter having been added to the specification in the form of a new sequence listing without a showing of the a description of the nature of the errors, when they were discovered, and an exhibition of due diligence in correcting them.

This application contains withdrawn claims 1-7 drawn to an invention nonelected with traverse in the reply filed on 14 February 2002. A complete reply to the Quayle

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action must include cancellation of nonelected claims or other appropriate action (37

CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Borgeest whose telephone number is (571)272-4482. The examiner can normally be reached on 8:00am - 2:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christina Borgeest, Ph.D.

/Elizabeth C. Kemmerer/

Primary Examiner, Art Unit 1646